Avantor, Inc.
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

Propylene Glycol

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
J.T.Baker®	9402	Propylene Glycol U.S.P. - F.C.C.	R
J.T.Baker®	9403	Propylene Glycol, U.S.P. Multi-Compendial	R
J.T.Baker®	9404	Propylene Glycol, U.S.P. Multi-Compendial	R
Macron Fine Chemicals™	6263	Propylene Glycol U.S.P. - F.C.C.	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product(s) listed in Section 1 are manufactured under current Good Manufacturing Practices (cGMPs) as set forth by ICH Q7 and International Pharmaceutical Excipients Council (IPEC) guidelines.

A number of the cGMP produced products that are sold by Avantor may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO and cGMP procedures in place at our facilities, we can ensure, and take complete responsibility for, the traceability and quality of the finished, packaged product that we offer.

For J.T.Baker® and Macron Fine Chemicals™ brand products, the Original Manufacturer and address will be referenced on the Certificate of Analysis as an alpha or alpha-numeric **manufacturer code** rather than listing the full name and address. This practice is compliant with both ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients (APIs) and IPEC guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult the Avantor website. Instructions can be found by visiting the Ask Avantor link under the Resources tab or by directly linking to www.askavantor.com Keyword: Manufacturer Code. Additional information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 7 for additional supplier information inquiries.

Section 3 – Physical/Chemical Information

CAS #: 57-55-6

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

DMF: Avantor may hold Master File(s) for specified product codes, dependent on the country of interest. Inquire with the support contact in Section 7 for additional details.

BSE/TSE Status: The subject materials are manufactured from raw materials that contain NO animal parts, products, and/or by-products nor do they come in contact with animal parts, products, and/or by-products.

Allergen/Hypersensitivities Information: To the best of our knowledge, the allergens listed in the US FDA, EU Directive 2003/89/EC, and TG0-91/92 are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer of product codes 9402, 9403, and 9404; all cereals, nuts or nut products, soybeans or soybean products, malt, or gluten (barley, oats, rye, triticale, spelt, kamut, or wheat); vegetables or fruits including all berries; milk or dairy products; crustacean or crustacean products; eggs or egg products; fish or fish products; or other allergens such as latex, natural rubber, cotton seed, sesame seed, mustard (seed, flour, oil, or other sources of mustard protein), poppy seed, sunflower seed, other legumes, lupin, mollusks, celery, rice, buckwheat, alcohol, trans fatty acids, partially hydrogenated oils, sulfur dioxide or sulfites, MSG, denatonium benzoate, formaldehyde, ethylene glycol, diethylene glycol, phenylalanine, melamine, ractopamine, enzymes, colors, or other preservatives are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer of product code 6263, allergens listed below from the European Union's Scientific Committee on Cosmetic and Non-Food Products opinion concerning fragrance allergy in consumers, SCCNFP/0017/98, listed in annex 3 of Directive 2003/15/EC, and food allergens as listed in Annex IIIa of Directive 2003/89/EC and subsequent amendments: Amyl cinnamal (amyl cinnamic aldehyde), Benzyl alcohol, Cinnamyl alcohol, Citral, Eugenol, Hydroxy-citronellal, Isoeugenol, Amylcin namyl alcohol, Benzyl salicylate, Cinnamal (cinnamic aldehyde), Coumarin, Geraniol, Hydroxy-methylpentylcyclohexenecarboxaldehyde, Anisyl alcohol, Benzyl cinnamate, Farnesol, 2-(4-t-Butylbenzyl)propionaldehyde (Lilial), Linalool, Benzyl benzoate, Citronellol, Hexyl cinnam-aldehyde, D-Limonene, Methyl heptine carbonate, 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one (gamma-Methylionone), Oak moss extracts, Treemoss extract, and known food allergens and products thereof such as: Cereals containing gluten, Crustaceans, Eggs, Fish, Peanuts, Soybeans, Milk, Nuts, i.e.

Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut,, Celery, Mustard, Sesame seeds, Sulphur dioxide and Sulphites, Lupine, Mollusks, and Latex are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.
Neither Avantor does not produce any of the following types of products: antibiotics, aflatoxins, penicillin, semi-synthetic penicillins, cephalosporins, other beta-lactams, cytotoxics, steroids, medicated feeds, or pesticides.

This product is manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants. However, this product is not tested for the presence of these or any other allergens by Avantor, therefore, we do not have confirmation for the absence of any allergens in the product.

GMO Information: The subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

Residual Solvents/Organic Volatile Impurities (OVI) Information: The subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

Elemental Impurities: Please see attached summary for Elemental Impurity information for listed products.

Kosher Status: Certified Kosher – Pareve for year-round use. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Kosher).

Halal Status: The subject materials are not Halal Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on Ask Avantor for our most up to date listing of Halal products. (www.askavantor.com Keyword: Halal).

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that Propylene Glycol (CAS # 57-55-6) is a Substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1(b)(1). For the latest information on whether or not an Avantor product is considered GRAS, please visit the Electronic Code of Federal Regulations.

Nutritional/Supplement Facts Labeling: The product codes 9402 and 6263 listed in Section 1 are bulk food chemicals that are intended for the use in manufacturing of finished food products or for products that are to be processed, labeled, and/or repacked at a site other than where it's originally processed or packed and are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements (21 CFR 101.9(j)(9)).

Organic Status: The products codes 9402 and 6263 listed in Section 1 are not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the Certificate of Analysis are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-10-01.

Lot Numbering System and Batch Description: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Ask Avantor for information concerning our lot/batch numbering system. (www.askavantor.com Keyword: Lot Number).

Batch Definition: A "batch" is a homogeneous unit of production; each batch of is from one single batch of the source supplier.

Shelf-Life Information: If a product has an assigned expiration or retest period, the date will appear on the Certificate of Analysis. For products that do not have assigned dates, please reach out to the support contact in Section 7 for additional stability inquiries.

Management of Change: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Management of Change link under the Working with Avantor tab on the Avantor website.

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. If you require further documentation, please reach out to the Trade Compliance support contact in Section 7.

Storage Requirements: Please refer to the product's Certificate of Analysis or Product Specifications. In the absence of specific storage conditions listed on its specification sheet or Certificate of Analysis, products are to be stored in ambient conditions of temperature and humidity. We do not formally tie any specific temperature or humidity range with the "ambient" storage designation, but an example of a common temperature interpretation is 15-30°C. Our products are also packaged to protect from the normal variation in humidity during storage and shipment. Further handling and storage information may be found in Section 7 of the product's SDS sheet.

Certificates of Analysis: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current list of product specifications using the Certificate/SDS Search tool on our website here.

Safety Data Sheet: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current product safety information using the Certificate/SDS Search tool on our website here.

Avantor Site Certifications: Please see the current Avantor site certifications on our website here.

Site Quality Overview: Avantor maintains a self-assessment modeled after IPEC guidelines which describes site and quality system information to support the manufacturing activities of this product. Please reach out to the support contact in Section 7 for a current copy of the Site Quality Overview.

Packaging Information: Please reach out to the support contact in Section 7 for current packaging specifications.

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Oct. 22, 2008 – Section 4: updated residual solvents information
Rev. 2; Apr. 19, 2011 – Entire document: new letterhead and changed all references of "Solv IT Center" to AskAvantor." Updated website links for new website; minor formatting; Section 1: changed Mallinckrodt to Macron added MOC column; Section 2: added GMP statement; Section 4: added GRAS statement; Section 5: added Nutritional and Organic statements; Section 7: updated contact information. (PH, JLW)
Rev. 3; Dec 27, 2012 – HDQ address change; Entire document: updated website links to new Avantor website; minor formatting; Section 1: added MOC codes; Section 2: added GMP statement; Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement Section 5: added Management of Change information; Added COA Date Format statement; Section 7: removed contact list table and added CS/TS contact information. (JDR)
Rev. 4; Jan. 8, 2016 – Section 4: Updated EMEA Residual Metallic statement to reflect current guideline revision. (MCH)
Rev. 5; Nov. 03, 2017 – Update document to new format. Section 4: added Elemental Impurity Statement. (PT)
Rev. 6; November 16, 2018 - Entire Document: New Format. (EC)
Rev. 7; January 26, 2021 – Entire Document: Minor formatting. Updated website and email addresses from avantorinc.com to avantorsciences.com; Section 1: Added product code 9404 in accordance with NPSU-2051; Section 4: Updated DMF and Allergen/Hypersensitivities Information statements. Added product code 9404 to Elemental Impurity assessment; Section 5: Nutritional/Supplement Facts Labeling and Organic Status statements updated to specify product codes and moved to Section 4 (previously in Section 5). (KH)
Rev. 8; February 16, 2023 – Added updated Elemental Impurity Report (SS)

This electronic document is valid without a signature.

Section 7 – Contact Information

Technical Service

Phone: 1-855-282-6867 and 1-610-573-2600 (outside U.S.), select option 5
Email: Technical.Service@avantorsciences.com

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: Trade.Compliance@avantorsciences.com

The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes or as part of the supplier audit cycle and managed under a validated document control sys

Avantor, Inc.
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

Material Name: Propylene Glycol **Product codes**: 9402, 9403, 6263 **Date**: September 9, 2022
Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

No Class 1, 2A, 2B, or 3 elementals are intentionally added to the production process.

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Not Tested	Manufacturer supplied data – Process Knowledge, Not Used in Production
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Not Tested	Manufacturer supplied data – Process Knowledge, Not Used in Production
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Not Tested	Manufacturer supplied data – Process Knowledge, Not Used in Production
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Not Tested	Manufacturer supplied data – Process Knowledge, Not Used in Production
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Not Tested	Manufacturer supplied data – Process Knowledge, Not Used in Production
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Manufacturer supplied data – Testing and Process Knowledge

Reference: ICH Q3D Guideline for Elemental Impurities, current revision

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department
Avantor™ Performance Materials, LLC